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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/688,090      | 10/17/2003  | Rubinah K. Chowdhary | 273012011601        | 9064             |

25225 7590 04/27/2005

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EXAMINER

FUBARA, BLESSING M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1618

DATE MAILED: 04/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  |   |   |  |
|--|---|---|--|
| <p align="center"><b>Office Action Summary</b></p> | <p><b>Application No.</b></p> <p align="center">10/688,090</p>  | <p><b>Applicant(s)</b></p> <p align="center">CHOWDHARY ET AL.</p> |  |
|  | <p><b>Examiner</b></p> <p align="center">Blessing M. Fubara</p> | <p><b>Art Unit</b></p> <p align="center">1618</p>                 |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,7-14,18,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,7-14,18,19 and 21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>1/26/05</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of corrected drawings, request for extension of time, amendment and remarks filed 01/26/05. Claims 1, 7-14, 18, 19 and new claim 21 are pending.

#### ***Drawings***

1. The corrected drawings are received and these drawings are acceptable.

#### ***Information Disclosure Statement***

The information disclosure filed 01/26/05 cites applications as prior art. Applications are not prior art and those applications have not been considered.

#### ***Claim Rejections - 35 USC § 112/NEW MATTER REJECTION***

2. The rejection of claim 18 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is not maintained in light of applicants' argument. However, it is respectfully noted that applicants are claiming what is excluded from their invention and applicants may specifically claim what is included in the invention and what the invention is and not what the invention is not.

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter,

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The photosensitizer carrier composition comprises (a) one or more photosensitizer and (b) one or more block copolymer. The specification does not describe that the carrier composition is a solid and the section of the specification applicants rely on (page 4, lines 4-6) does not state that the carrier composition is a solid. Specifically, the section of the specification cited by applicants indicate that a complex formed from the photosensitizer and block copolymer may be converted to solid form for storage or be hydrated with an aqueous solution for storage.

Claim 21 is rejected under 35 U.S.C. 112, first paragraph as containing new matter. Hydratable support has no support in the specification as originally filed. The section of the specification, page 4, lines 12-14 states: "furthermore, the invention provides compositions and methods for formulating a photosensitizer drug and block copolymer complex deposited on or encapsulated by a solid-support. Hydration of the complex results in a non-aggregated photosensitizer drug formulation." The solid support is not hydrated, rather, it is the complex that is hydrated and the complex is encapsulated by the solid support.

5. Claims 7 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Amended claim 1 now requires that the carrier composition be in a solid form. Claim 7 is also requiring that the complex formed between the photosensitizer and the

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block copolymer be a micelle, emulsion or a gel. Micelle or emulsion is not a solid.

Thus it is not clear what applicants want the carrier composition to be, a solid or emulsion or liquid? The carrier composition cannot be a solid in claim 1 and then an emulsion or micelle in dependent claim 7.

#### **¶ 8.04 Election by Original Presentation**

Newly submitted claim limitation of “solid form” is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Applicants elected emulsion or micelle by original presentation since dependent claim 7 defined the carrier composition as emulsion or micelle and claiming a solid for the carrier now changes the scope of the original claim 1.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Therefore, the claims as originally presented as an emulsion or micelle is examined. Secondly, applicants in the remarks admit that the solid form is different from a liquid or emulsion, a claim now to a solid form is a distinct invention from a claim directed to an emulsion or micelle.

#### ***Claim Rejections - 35 USC § 102***

6. Claims 1, 8 and 10 remain rejected under 35 U.S.C. 102(a) as being anticipated by Rajagopalan et al. (WO 99/51284, reference provided by applicants in Form PTO 1449).

Applicants argue that Rajagopalan discloses a liquid form and not the solid form, and that the solid form is distinct from the liquid form.

7. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive. While examiner agrees with applicants that a liquid is not a solid, it is

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respectfully submitted that the invention as originally presented is an emulsion, which as acknowledged by applicants is distinct from a solid. Since applicant has received an action on the merits for the originally presented invention, applicant has constructively elected by original presentation for prosecution on the merits the claim to emulsion or micelle. The rejection is thus maintained.

***Claim Rejections - 35 USC § 103***

8. Claims 1 and 7-14 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342).

9. Claims 18 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lyons (US 5,616,342).

Applicants argue that a) Lyons discloses liquid emulsions and Lyons had not provided that the emulsion can be converted to solid form, b) there is no motivation to modify the liquid emulsion to solid form and c) Lyons does not disclose poloxamer 188 with a disclosure of poloxamer genus.

10. Applicants' arguments filed 01/26/05 have been fully considered but they are not persuasive.

11. Regarding a) and b), the invention as originally presented is an emulsion, which is acknowledged by applicants to be distinct from a solid. Since applicant has received an action on the merits for the originally presented invention, applicant has constructively elected by original presentation for prosecution on the merits the claim to emulsion or micelle. The rejection is thus maintained. Regarding c), Lyons do not exclude poloxamer 188 and a generic and broad disclosure of poloxamer encompasses all the

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various forms of poloxamer to the extent that Lyons does not exclude or include the use of the specific poloxamer 188. A genus may not anticipate the specie when the genus has a large number of species. In *in re Petering*, 301 F.2d 676, 681, 133 USPQ 275, 280 (CCPA 1962) it is noted that when the genus is small, and when considered in light of the totality of the circumstances, the genus would anticipate the claimed species or subgenus. In the present case, the number of types of poloxamer is finite and the skilled artisan would be able to use any of the poloxamers including the poloxamer 188.

No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571)

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272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BF

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